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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,307	04/12/2001	Richard J. Whitbourne	32286-192724	3036

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/834,307	WHITBOURNE ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-67 and 69-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-67 and 69-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/22/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Remarks and Declaration Under 37 CFR 1.132 dated 2/22/08

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 23-52,56-59,61-65,67,69-71,74,76-78 and 80-83 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Eder et al (USPN 5,980,550 hereafter '550) in view of Whitbourne et al (USPN 6,110,483 hereafter '483). The claims are drawn to a medicated device comprising a scaffold with defined edges along the surface that create openings, wherein a coating is applied that bridges said openings.

4. The '550 patent discloses a coated vascular implant comprising a water-soluble coating (abstract). The implant comprises a substrate and a coating wherein the coating comprises active agents that are delivered to the patient (col. 3, lin. 30-45). The implant has a coil shape where

the edges of the coils form opening between them. The edges are bridges by the coating material (Figure 2 204). The coating connects the edges of the coils (Figures 2). The coating can comprise generally approved as safe polymers such as polyethylene glycol, polyvinylpyrrolidone, polyvinyl alcohol and polyesters (col. 5, lin. 5-21). The implant comprises multiple layers (col. 5, lin. 60-68). The coatings con comprise both hydrophobic and hydrophilic polymers (col. 6, lin. 1-5). The stent comprise active agents such as aspirin and heparin (col. 6, lin. 10-15). The reference is however silent to the active agent loading of the implant. This loading is well known in the art and can be seen in the '483 patent.

5. The '483 patent discloses a medical device comprising a substrate with a coating (abstract, col. 5, lin. 58-65). The substrates include commonly difficult substrates to coat such as wires, needles, urethral inserts and other implantable objects (*Ibid.*). The coating material comprises both hydrophilic and hydrophobic polymers such as N-vinylpyrrolidone (col. 5, lin. 13-39) and acrylic polymers (col. 6, lin. 5-16) as well as vinyl acetate (*Ibid.*), as well as polyvinylpyrrolidone/vinyl acetate copolymers (col. 3, lin. 38-50). The coating comprises pharmaceutical agents including rifamycin, and heparin complexes with benzalkonium chloride (col. 8, lin. 59-col. 9, lin. 28). The coatings, as a result of the drying process, intermingle with the substrates (col. 10, lin. 36-40). The coating composition has a thickness of about less than 50 microns (col. 7, lin. 15-20). According to applicant's specification a 10-micron thick coating would correspond to a 1000 microgram/cm^3. The thickness of this coating would possess a loading amount well within the limits of the claimed invention. The reference discloses various methods of making the medical device including dipping, spraying and other well-known coating methods (col. 2, lin. 60-68). Though silent to the specific design of the substrates regarding their

edges and surfaces, the coating is a continuous coating over each surface (col. 4, lin. 18-30). Applicant is invited to provide evidence that the continuous coating of the invention does onto cover the edges and bridge surfaces.

6. Regarding claims 41 and 42, it is the position of the examiner that such limitations do not impart patentability to the claim. The reference discloses a polyvinylpyrrolidone/vinyl acetate copolymer as a possible coating material. It would be well within the limits of ordinary skill in the art to determine the optimal component ranges operation for the polymer coating giving the general conditions of the specification. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

7. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

8. With these things in mind it would have been obvious to a skilled artisan to follow the suggestions of the art to produce a medical article with a continuous coating over all surfaces with a high loading concentration. It would have been obvious to include the active agent loading of the ‘483 patent into the coated coil of the ‘550 patent in order to provide sufficient active agent able to provide sustained release and treatment. One of ordinary skill in the art would have been motivated to follow these suggestions in order to provide a coated medical

device that is flexible, and resist wet abrasions. It would have been obvious to follow these suggestions with an expected result of a coated medical device.

9. Claims 50,53-55,60,61,66,72-75,77 and 79 rejected under 35 U.S.C. 103(a) as being patentable over the combined disclosures of Eder et al (USPN 5,980,550 hereafter '550) and Whitbourne et al (USPN 6,110,483 hereafter '483) in view of Kamath et al (USPN 6,335,029 hereafter '029) and Khan et al (USPN 5,589,120 hereafter '120). The claims are drawn to a medical device comprising a substrate and a coating. The substrate is a coil, and the coating further comprises paclitaxel and other active agents.

10. As discussed above the '483 patent discloses a medical device comprising a substrate and a coating. The substrates include wires, stents, and other implants (col. 2, lin. 31-38). The reference is however silent to the inclusion of coils as possible substrates. The reference is also silence to the inclusion of paclitaxel. However the inclusion of this antibiotic is well within the level of skill in the art, since many antibiotic agents are mentioned and suggested by the '483 reference. Their inclusion in a medical device is well within the art as seen in the '029 reference.

11. The '029 reference discloses a coated medical device comprising a substrate and a coating with antibiotics agent incorporated therein (abstract). The substrates may include coils, (col. 2, lin. 45-50), biocompatible polymer coatings such as polyvinylpyrrolidone (col. 6, lin. 28-50), and antibiotics such as paclitaxel (col. 5, lin. 54-65). Following these teachings a skilled artisan would have been motivated to include paclitaxel in to the coating compositions of '483. A skilled artisan would have further been motivated to apply the coatings to a coiled substrate following the suggestions of '029.

12. Likewise as shown in the '120 reference, which teaches a coated implant comprising various antibiotics such as polyhexamethylene biguanide hydrochloride (col. 3, lin. 51-55). A skilled artisan would have been motivated to combine the agents of the '120 with the coatings in order to impart biocidal properties on the implant of '483.

13. With these things in mind a skilled artisan would have been motivated to apply coating compositions to coiled substrates as taught and suggested by '029, or '120. A skilled artisan would have been motivated to continuously coat the coil as taught by '483 in order to provide a medical device with a coating that is flexible, and resist wet abrasions. A skilled artisan would have been motivated to include paclitaxel into the coatings of '483 as shown in '029 and '120 in order to further treat more bacterial infections. It would have been obvious to a skilled artisan to combine these teachings and suggestions with an expected result of a medical device with a flexible, and stable coating capable of treating various bacterial infections.

Response to Amendment

The Declaration filed under 37 CFR 1.132 filed 2/22/08 is insufficient to overcome the rejection of claims 23-67 and 69-83 based upon USC 103 as set forth in the last Office action because: The Declaration is not commensurate in scope with the instant claims and provides no direct actual comparison between the prior art. The Declaration provides a theoretical schematic drawing showing what is alleged as actual "correct" interpretation of the Eder drawing. The Declaration presents no accompanying statement form the Eder inventors in support of this allegation, or any evidence to support this drawing other the opinions of the instantly named inventors. The arguments in the Declaration provide no solid evidence to support the proposed

drawing. The Declaration also provides no comparison between the actual drawing or invention of the Eder patent and the invention of the instant claims. For these reasons the Declaration is insufficient to overcome the rejection.

Response to Arguments

Applicant's arguments filed 2/22/08 have been fully considered but they are not persuasive. Applicant argues that:

> The combination of the Eder and Whitbourne patents do not discloses the coating bridging of the instant claims and thereby does not obviate the claims.
>
> The combination of the Eder, Whitbourne, Kamath and Khan patents do not further obviate the claims since the bridged coating of the instant claims is not taught.

Regarding the first argument, it remains the position of the Examiner that the combination of the Eder and Whitbourne patents continue to obviate the claims. Applicant argues that the Figures of Eder are "incorrect" and do not represent the 3-dimensional nature of the invention. Applicant provides a “correct” schematic showing that the outer coating of the Eder implant does not provide the bridging of the instant claims. As discussed above, it remains the position of the Examiner that first the "correct" schematic presented and relied upon by Applicant has no bearing whatsoever on the patentability of the claims. The drawing has no support anywhere in the prior art and Applicant has provided no factual evidence to support how this schematic is more "correct" than those of the Eder patent. As such it remains the position of the Examiner that the Eder patent continues to obviate the claims. The Eder patent provides an implant with a coiled structure, where the outer coils creates edges that are in close proximity to

each other. These close proximity edges are covered with an outer coating that as seen Figure 2. The outer coating protects the inner drug deliver coating and dissolves after the implantation. Since the outer coating is used to reduce friction and provide thrombosis relief, it would be obvious to coat the coil ion the exterior only since those surfaces would be in most contact with the surrounding tissue (col. 5, lin. 55-68). There would be no reason to have reduced friction the interior of the coil since it does not contact tissue for implantation. It remains the position of the Examiner that the Figures of the Eder patent are an accurate depiction of an outer coating covering a coil and bridging the gaps created in the winding of the coil. The outer coating covers and bridges the opening of the implant coil and thereby obviates the instant claims. The Whitbourne patent provides the specific coating concentrations. Since the outer coating of the Eder patent and those of the Whitbourne patent are similar it would have been obvious to include the coating concentrations of the Whitbourne implants onto those of the Eder patent in order to ensure complete coverage and sufficient protection of the underlying drug coating layers. The Whitbourne patent also discloses specific active agents that would be helpful during an implantation procedure. It would have been obvious to make this combination, and as such the claims remain obviated.

Regarding the second argument, it remains the position of the Examiner that the combination of the Eder, Whitbourne, Kamath and Khan patents continue to ovate the claims. As discussed above the combination of the Eder and Whitbourne patents obviate the claims. The combination is silent to specific active agents or polymers of the instant claims, although similar polymers and active agents are used. The Kamath patent provides a polyvinylpyrrolidone coating as well as paclitaxel, while the Khan patent provides specific antibiotics such as

polyhexamethylene biguanide hydrochloride. It would have been obvious to include these compounds into the combination of the Eder and Whitbourne patent since each patent provides a coated implant within the same field of endeavor. These would be simple substitutions that are well within the level of skill in the art. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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